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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,633	10/29/2003	Mary K. Hart	ARMY144	7713

7590

06/15/2004

U.S. Army Medical Research and Materiel Command
504 Scott Street
Ft. Detrick, MD 21702-5012

EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/696,633

Applicant(s)

HART ET AL.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,33,34 and 45-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 28,33,34 and 45-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's preliminary amendment filed October 29, 2003 is acknowledged and entered.

Claims 28, 33, 34 and 45-60 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 28 and 59, drawn to a DNA construct, classified in class 435, subclass 320.1.
 - Further restriction is required in claim 59. Applicant must elect one DNA construct since the constructs in claim 59 produce different proteins, which are separately patentable. If a construct other than VrepEboVP35 is elected, then claim 28 will be withdrawn from consideration.
- II. Claims 33 and 58, drawn to RNA, classified in class 536, subclass 23.1.
- III. Claims 34 and 56, drawn to alphavirus particles, classified in class 424, subclass 218.1.
- IV. Claims 45, drawn to a method for producing Ebola virus protein, classified in class 435, subclass 69.1.
- V. Claim 46, drawn to an Ebola GP protein, classified in class 424, subclass 218.1.
- VI. Claim 47, drawn to an Ebola NP protein, classified in class 424, subclass 218.1.
- VII. Claim 48, drawn to an Ebola VP24 protein, classified in class 424, subclass 218.1.
- VIII. Claim 49, drawn to an Ebola VP30 protein, classified in class 424, subclass 218.1.

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- Further restriction is required in claim 49. Applicant must elect one sequence for examination. SEQ ID NO: 20 and 23 have different amino acid sequences, which require separate searches.
- IX. Claim 50, drawn to an Ebola VP35 protein, classified in class 424, subclass 218.1.
- X. Claim 51, drawn to an Ebola VP40 protein, classified in class 424, subclass 218.1.
- XI. Claim 52, drawn to an antibody to a peptide, classified in class 424, subclass 130.1.
- Further restriction is required in claim 52. Applicant must elect one sequence for examination. Antibodies to different proteins are separately patentable products because they bind to different epitopes.
- XII. Claim 53 and 57, drawn to a method for detecting virus using an antibody, classified in class 435, subclass 5.
- Further restriction is required if Group XII is elected because claims 53 and 57 depend ultimately from claim 52. Claim 52 is subject to further restriction, for the reasons above. Applicant must elect one sequence from claim 52.
- XIII. Claim 54, drawn to a method for detecting Ebola GP RNA, classified in class 435, subclass 4.
- XIV. Claim 55, drawn to a nucleic acid sequence, classified in class 536, subclass 24.33.
- XV. Claim 60, drawn to a peptide, classified in class 530, subclass 300.

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- Further restriction is required in claim 60. Applicant must elect one sequence for examination. SEQ ID NO: 24 and 25 have different amino acid sequences, which require separate searches.

The inventions are distinct, each from the other because of the following reasons:

- a) Inventions I, II, III, V-XI, XIV and XV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to DNA, RNA, virus particles, proteins and antibodies. These products are structurally and chemically distinct. The proteins of inventions V-X and XVI are drawn to different proteins, having different amino acid sequences. The nucleic acid of invention XIV is distinct from the DNA construct of invention I. These products have different modes of operation, function and effect. The products are not disclosed as capable of use together.
- b) Inventions (I, II and III) and (IV, XII and XIII) are unrelated. The methods of inventions IV, XII, XIII and XV do not require the DNA construct of invention I, or the RNA of invention II, or the particle of invention III.
- c) Inventions IV, XII and XIII are unrelated. The methods are drawn to producing virus proteins, detecting virus with antibodies and detecting RNA. These methods do not share modes of operation, function or effect. The methods are not disclosed as capable of use together.
- d) Inventions IV and (V-XI, XIV and XV) are unrelated. Invention IV is drawn to a method for producing virus proteins. The proteins, antibodies, nucleic acid and peptide are not disclosed as capable of use together.

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e) Inventions XI and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used in a method of inducing an immune response.

f) Inventions XIII and (V-XI and XV) are unrelated. The method of invention XIII is drawn to detecting Ebola GP RNA. The products of inventions V-XI and XV are not required for practicing the method of detection.

g) Inventions XII and (V-X, XIV and XV) are unrelated. The method of invention XII is drawn to detecting virus. The products of inventions V-X, XIV and XV are not required to practice the method of detecting.

h) Inventions XIII and XIV are related as product and process of use. In the instant case the nucleic acid can be used in a materially different method of using, such as a method of inducing an immune response.

Because these inventions are distinct for the reasons given above and the sequence search required for one group is not required of co-extensive for any other group and therefore burdensome, restriction for examination purposes as indicated is proper. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

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inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

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claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SBC

Stacy B. Chen
June 7, 2004

James C. Housel
JAMES HOUSEL 6/13/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600